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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,857	01/23/2002	B. Nash Williams		3074

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,857	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In view of the cancellation of claims 1-16, all rejections and objection to claims 1-16 are hereby withdrawn. New claims 17-28 are pending.

Specification

The abstract of the disclosure is again objected to because the first sentence is not complete. Applicant has not amended the abstract to overcome this objection, therefore the objection is maintained. Further, the claims no longer recite a device, therefore the abstract is objected to because it is not directed to the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Objections

Applicant is advised that should claims 17-22 be found allowable, claims 23-28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. It is noted that the claims recite identical method steps. As the preamble of each claim does not affect either the steps themselves nor the outcome/result of the claims, the claims are not patentably distinct. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

The claims are directed to a method of manipulating DNA information comprising steps (a)-(e). A method comprising these steps is literally supported by the specification on page 5. However, the specification does not describe any method steps for "analyzing" a DNA sample to identify an individual's "unique genetic sequence". This step encompasses decoding an individual's entire genome, discovering a "unique" mutation, detecting a SNP or RFLP, etc. none of which are described by the instant specification. The specification discloses on page 5 that a sample is "analyzed in the conventional manner" to determine the person's unique DNA sequence. As is well known in the art, as evidenced by extensive media coverage, there is no single "conventional method" for analyzing a sequence. As set forth by GUTTMAN et al. (TAC (1999) vol. 18 (11), pp. 694-702), at least one method of genotyping and genetic profiling requires at least a gel electrophoresis device and a scanning laser. Electrophoresis and use of a scanning laser are no disclosed by the instant specification. GOA et al. (Int'l Genome Sequencing an Analysis Conference (2000) vol. 12, pp. 60-61) teaches

a method of genotyping using microchips and specific software for analysis. As late as September of 2003, LUO et al. (Genomics (9/2003) vol. 82 (3), pp. 378-389) taught that DNA must be isolated from a sample, labeled, and subjected to restriction digestion in order to build a map of a genome. WALLIN et al. (J. Forensic Sciences (2002) vol. 47 (1), pp. 52-65) teaches use of multiplex PCR and fluorescence detection in methods to differentiate and distinguish human genetic profiles. No steps such as those taught by the prior art are disclosed by the instant specification as part of the inventive method. No apparatus or program for sequence comparison, or database comprising correlations of known genes to known disorders is disclosed by the instant specification, such that a "unique" genetic DNA sequence may be analyzed and correlated to specific physical conditions, is disclosed by the originally filed specification. Further, there is no disclosure for steps to generate a "unique genetic profile" as generation of a profile is not usually the result of merely comparing a genetic DNA sequence to a database. The specification fails to disclose what parameters are comprised within the DNA profile or what steps are necessary to generate the profile. Applicant is reminded that 37 CFR 1.75(d)(1) provides, in part, that "the terms and phrases used in the claims must find **clear support** or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable **by reference to the description**." Emphasis added by the examiner. As the instant specification fails to clearly describe any specific steps for performing the analysis and correlation claimed, the claims lack written description.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant argues in the response filed 6/24/04 that annotating "each gene" is human genome is presently being done, therefore one skilled in the art would "fully understand" the steps required to analyze a gene sequence. In response, it is noted that teachings by the prior or present art can not supply or substitute for a full and complete written description of the instantly claimed invention.

Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the specification or the prior art teach how to perform the claimed method. The specification provides no guidance with regard to steps for analyzing a genetic sample, identifying a "unique" genetic DNA sequence, or correlating a "unique" genetic profile with a specific physical condition. The prior art does provide guidance for analyzing

specific DNA sequences, wherein the steps and materials used are subject to the type of information desired, as set forth above. It is clear from the teachings of the prior art that a DNA sample must first be isolated from a biological sample before any sequence analysis can be preformed. The claims do not recite any steps or means for isolating DNA, nor does the specification disclose any such steps or means. Next, some sort of sequence, hybridization, or fragment analysis must be performed to identify the DNA isolated. Every individual necessarily comprises a "unique" genome; i.e. the combination of genes which make up the entirety of the genome renders the individual. However, not every gene carried by an individual is "unique". In fact, most humans carry many genes which are identical; e.g. those coding for necessary metabolic enzymes. It is acknowledged that most humans carry different alleles for various genes, such as for eye color, and that specific alleles may comprise SNP or other mutations rendering the particular allele different from those carried by the majority of humans. However, an allele is not necessarily "unique" for an individual, just different from a majority. For example, Elizabeth Taylor is well known to have unusual violet eyes, but they are not "unique"; there are other individuals with violet eyes in the human population. The mutation associated with Huntington's chorea is not carried by a single individual, but may be found in disparate families (populations), and is therefore not a "unique" mutation specific to an individual. Further, since expression of a physical trait is often the result of a concatenation of events comprising the expression (or disturbed expression) of multiple genes, or requires interaction between multiple gene products, it is not

clear form the teachings of the specification how one would correlate a single "unique" gene with a physical trait. Further, if one were to consider the entire genome and the "unique" genetic DNA sequence, then it is unclear from the teachings of the specification how one is to correlate an entire genome with a specific physical condition. If the gene sequence is intended to be truly "unique"; i.e. one possessed by the individual alone, then it is impossible to correlate that sequence with physical condition by using a database, as the "unique" sequence would not yet have been added to a database or annotated.

The specification does not set forth any working examples. The single Figure is a drawing of a computer workstation and does not show any specific attributes for performing the functions/steps set forth in the claims. The level of skill in the art is acknowledged to be high. However, due to the lack of guidance in the specification, and the high level of variability/uncertainty in the art for how to analyze DNA and correlate sequences with physical conditions as previously set forth, or how to identify and correlate a "unique genetic DNA sequence with any physical condition, it would require undue experimentation for one skilled in the art to use the claimed apparatus or perform the claims method.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant argues in the response filed 6/24/04 that annotating "each gene" is human genome is **presently** being done, therefore one skilled in the art would "fully understand" the steps required to analyze a gene sequence. In response, it is noted that the claims must be enabled at the time of filing, therefore the argument that work is

ongoing is support for the examiner's position that the claimed method was and is not enabled.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 23 recite the term "unique" with regard to a DNA sequence. It is unclear what applicant intends this term to mean, therefore the claims are indefinite. As set forth above, the term "unique" as applied to a DNA sequence may have many meanings in the art and the specification does not set forth any particular definition for the term. As the metes and bounds intended by applicant for a "unique" DNA sequence are not clear, the claims are rejected.

Conclusion

Claims 17-28 are rejected; the abstract is again objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
9/30/04